

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

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<b>CHARLES A. BUIE and MARY C. HALFACRE-</b>	:	
<b>BUIE h/w; DAVID J. IRVINE and BARBARA</b>	:	
<b>IRVINE, h/w; DONALD A. KELLER and GAIL S.</b>	:	
<b>KELLER, h/w; RALPH L. KOHR, III and</b>	:	
<b>ARLENE S. KOHR, h/w; and GARY P.</b>	:	Case No.: 08-cv-3833 (DAB)
<b>SCHNEIDER and PATTI SCHNEIDER, h/w,</b>	:	
	:	
<b>Plaintiffs</b>	:	<b>ANSWER AND DEFENSES OF</b>
	:	<b>PFIZER INC.</b>
<b>vs.</b>	:	
	:	<b>(ECF)</b>
<b>PFIZER INC.,</b>	:	
	:	
<b>Defendant.</b>	:	

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Pfizer Inc. (hereinafter “Pfizer” or “Defendant”), as and for its answer and defenses to the complaint (hereinafter “Complaint”) filed by Plaintiffs pleads as follows:

**PARTIES-PLAINTIFFS**

1. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 1 of the Complaint.
2. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 2 of the Complaint.
3. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 3 of the Complaint.
4. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 4 of the Complaint.
5. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 5 of the Complaint.

**PARTIES-DEFENDANT**

6. Pfizer admits that it is incorporated in the state of Delaware and that its principal place of business is located at 235 E. 42<sup>nd</sup> Street, New York, New York 10017.

7. Pfizer denies each and every allegation contained in Paragraph 7 of the Complaint, except admits that it designed, manufactured, and, following FDA approval, marketed, and/or distributed Viagra<sup>®</sup> for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

8. Pfizer admits that it is authorized to do business in the state of New York.

9. Pfizer admits that it conducts business within the state of New York.

10. Pfizer denies each and every allegation contained in Paragraph 10 of the Complaint, except admits that it has marketed and/or distributed Viagra<sup>®</sup> for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein, including in the state of New York, and Pfizer further admits that Viagra<sup>®</sup> was approved by the FDA for the treatment of male erectile dysfunction.

11. Pfizer admits that it receives revenue in the state of New York.

12. Paragraph 12 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 12 of the Complaint.

### **GENERAL BACKGROUND AND OVERVIEW OF CLAIMS**

13. Pfizer denies each and every allegation contained in Paragraph 13 of the Complaint, except admits that Plaintiffs purport to bring this action for damages, but denies that they are entitled to any such relief.

14. Pfizer denies each and every allegation contained in Paragraph 14 of the Complaint, except admits that it designed, manufactured, and, following FDA approval, marketed, and/or distributed Viagra<sup>®</sup> for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

15. Pfizer denies each and every allegation contained in Paragraph 15 of the Complaint, except denies knowledge or information sufficient to form a belief as to the Plaintiffs' medical condition.

16. Pfizer admits that the medical conditions Non-Arteritic Ischemic Optic Neuropathy (NAION), Arteritic Ischemic Optic Neuropathy (AION), Posterior Ischemic Optic Neuropathy (PION), Ischemic Optic Neuropathy (ION), Branch Retinal Artery Occlusion (BRAO), and Central Retinal Artery Occlusion (CRAO) can lead to decreased vision or blindness.

17. Pfizer denies each and every allegation contained in Paragraph 17 of the Complaint.

18. Pfizer denies each and every allegation contained in Paragraph 18 of the Complaint.

19. Pfizer denies each and every allegation contained in Paragraph 19 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' use of Viagra<sup>®</sup>.

20. Pfizer denies each and every allegation contained in Paragraph 20 of the Complaint, except denies knowledge or information sufficient to form a belief as to the state of mind of Plaintiffs and/or their physicians.

21. Pfizer denies each and every allegation contained in Paragraph 21 of the Complaint, except denies knowledge or information sufficient to form a belief as to the Plaintiffs' use of Viagra<sup>®</sup>, their medical conditions, or their future needs.

22. Pfizer admits that Plaintiffs seek actual and punitive damages, but denies that Plaintiffs are entitled to any such relief. Pfizer denies the remaining allegations contained in Paragraph 22 of the Complaint, except denies knowledge or information sufficient to form a belief as to the Plaintiffs' use of Viagra<sup>®</sup>, their medical conditions, their state of mind, or their future needs.

### **JURISDICTION**

23. Paragraph 23 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies knowledge or information sufficient to form a belief as to the Plaintiffs' states of citizenship, but admits that based on the allegations in the Complaint, this Court has subject matter jurisdiction.

### **SUBSTANTIVE ALLEGATIONS**

24. Pfizer denies each and every allegation contained in Paragraph 24 of the Complaint, except admits that Viagra<sup>®</sup> is the trade name for the prescription drug sildenafil and admits that Viagra<sup>®</sup> was approved by the FDA for the treatment of male erectile dysfunction.

25. Pfizer admits that Viagra<sup>®</sup> is a phosphodiesterase inhibitor, and refers to the medical literature and the FDA-approved label for additional information on the pharmacology and mode of action of the drug.

26. Pfizer denies each and every allegation contained in Paragraph 26 of the Complaint, except admits that Viagra<sup>®</sup> was approved by the FDA on March 27, 1998 for the treatment of male erectile dysfunction.

27. Pfizer denies each and every allegation contained in Paragraph 27 of the Complaint, except admits that on July 8, 2005, the FDA issued a Statement, and refers to the Statement for the contents thereof. Pfizer further admits that the FDA approved updated labeling for Viagra<sup>®</sup> on or about July 8, 2005, and refers to that updated label for the contents thereof.

28. Pfizer denies each and every allegation contained in Paragraph 28 of the Complaint, except admits that on July 8, 2005, the FDA issued an Alert for Healthcare Professionals, and refers to the Alert for Healthcare Professionals for the contents thereof.

29. Pfizer denies each and every allegation contained in Paragraph 29 of the Complaint, except admits that the FDA approved updated labeling for Viagra<sup>®</sup> on or about July 8, 2005, and refers to the label for the contents thereof.

30. Pfizer denies each and every allegation contained in Paragraph 30 of the Complaint.

31. Pfizer denies each and every allegation contained in Paragraph 31 of the Complaint.

32. Pfizer denies each and every allegation contained in Paragraph 32 of the Complaint.

33. Pfizer denies each and every allegation contained in Paragraph 33 of the Complaint.

34. Pfizer denies each and every allegation contained in Paragraph 34 of the Complaint.

35. Pfizer denies each and every allegation contained in Paragraph 35 of the Complaint, and specifically avers that Viagra<sup>®</sup> is safe and effective when used in accordance with its FDA-approved label.

36. Pfizer denies each and every allegation contained in Paragraph 36 of the Complaint.

37. Pfizer denies each and every allegation contained in Paragraph 37 of the Complaint, except denies knowledge or information sufficient to form a belief as to the state of mind of the Plaintiffs or their physicians.

**EQUITABLE TOLLING OF APPLICABLE  
STATUTES OF LIMITATIONS:**

38. Paragraph 38 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 38 of the Complaint.

39. Pfizer denies each and every allegation contained in Paragraph 39 of the Complaint, except denies knowledge or information sufficient to form a belief as to the state of mind of Plaintiffs or their physicians.

40. Paragraph 40 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 40 of the Complaint.

41. Paragraph 41 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 41 of the Complaint, except denies knowledge or information sufficient to form a belief as to the economic resources or state of mind of Plaintiffs and “medical professionals.”

**COUNT I  
Negligence**

42. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 41 as if fully contained herein.

43. Paragraph 43 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 43 of the Complaint.

44. Paragraph 44 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 44 of the Complaint.

45. Pfizer denies each and every allegation contained in Paragraph 45 of the Complaint, including subparts (a) through (c) thereof.

46. Pfizer denies each and every allegation contained in Paragraph 46 of the Complaint.

47. Pfizer denies each and every allegation contained in Paragraph 47 of the Complaint.

48. Pfizer denies each and every allegation contained in Paragraph 48 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, or future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count I of the Complaint.

**COUNT II**  
**STRICT LIABILITY -- FAILURE TO WARN**

49. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 48 as if fully contained herein.

50. Paragraph 50 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 50 of the Complaint, except admits that it designed, manufactured, and, following

FDA approval, marketed, and/or distributed Viagra<sup>®</sup> for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

51. Paragraph 51 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 51 of the Complaint.

52. Paragraph 52 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 52 of the Complaint.

53. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 53 of the Complaint.

54. Paragraph 54 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 54 of the Complaint and specifically denies there is any defect.

55. Pfizer denies each and every allegation contained in Paragraph 55 of the Complaint, except denies knowledge or information sufficient of form a belief as to Plaintiffs' state of mind or their use of Viagra<sup>®</sup>.

56. Paragraph 56 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 56 of the Complaint.

57. Pfizer denies each and every allegation contained in Paragraph 57 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' state of mind.



58. Paragraph 58 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 58 of the Complaint.

59. Pfizer denies each and every allegation contained in Paragraph 59 of the Complaint.

60. Pfizer denies each and every allegation contained in Paragraph 60 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, and future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count II of the Complaint.

**COUNT III**  
**Strict Liability -- Defective Design**

61. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 60 as if fully contained herein.

62. Pfizer denies each and every allegation contained in Paragraph 62 of the Complaint, except admits that it designed, manufactured, and, following FDA approval, marketed, and/or distributed Viagra® for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

63. Pfizer denies each and every allegation contained in Paragraph 63 of the Complaint, except admits that it designed, manufactured, and, following FDA approval, marketed, and/or distributed Viagra® for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings,

and contra-indications and other information contained therein, and denies knowledge or information sufficient to form a belief as to Plaintiffs' purchase and/or use of Viagra®.

64. Paragraph 64 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 64 of the Complaint.

65. Pfizer denies each and every allegation contained in Paragraph 65 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' use of Viagra®.

66. Pfizer denies each and every allegation contained in Paragraph 66 of the Complaint, except admits that it designed, manufactured, and, following FDA approval, marketed, and/or distributed Viagra® for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

67. Pfizer denies each and every allegation contained in Paragraph 67 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, and future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count III of the Complaint.

**COUNT IV**  
**BREACH OF EXPRESS WARRANTY**

68. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 67 as if fully contained herein.

69. Paragraph 69 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 69 of the Complaint.

70. Paragraph 70 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 70 of the Complaint.

71. Pfizer denies each and every allegation contained in Paragraph 71 of the Complaint.

72. Paragraph 72 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 72 of the Complaint.

73. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 73 of the Complaint.

74. Pfizer denies each and every allegation contained in Paragraph 74 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, or future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count IV of the Complaint.

**COUNT V**  
**Breach of Implied Warranty**

75. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 74 as if fully contained herein.

76. Pfizer denies each and every allegation contained in Paragraph 76 of the Complaint, except admits that it designed, manufactured, and, following FDA approval,

marketed, and/or distributed Viagra<sup>®</sup> for use by prescription only through licensed physicians in accordance with FDA-approved prescribing information and subject to precautions, warnings, and contra-indications and other information contained therein.

77. Paragraph 77 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 77 of the Complaint.

78. Pfizer denies each and every allegation contained in Paragraph 78 of the Complaint, except denies knowledge or information sufficient to form a belief as the state of mind of Plaintiffs and the “medical community,” or as to Plaintiffs’ use of Viagra<sup>®</sup>.

79. Paragraph 79 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 79 of the Complaint.

80. Paragraph 80 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 80 of the Complaint, except denies knowledge or information sufficient to form a belief as to the state of mind of Plaintiffs and/or the “medical community.”

81. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 81 of the Complaint.

82. Pfizer denies each and every allegation contained in Paragraph 82 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs’ medical conditions, economic losses, or future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count V of the Complaint.

**COUNT VI**  
**Common Law Fraud**

83. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 82 as if fully contained herein.

84. Pfizer denies each and every allegation contained in Paragraph 84 of the Complaint.

85. Pfizer denies each and every allegation contained in Paragraph 85 of the Complaint.

86. Pfizer denies each and every allegation contained in Paragraph 86 of the Complaint.

87. Pfizer denies each and every allegation contained in Paragraph 87 of the Complaint.

88. Pfizer denies each and every allegation contained in Paragraph 88 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' use of Viagra<sup>®</sup>.

89. Pfizer denies each and every allegation contained in Paragraph 89 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' state of mind or their medical conditions.

90. Pfizer denies each and every allegation contained in Paragraph 90 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, or future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count VI of the Complaint.

**COUNT VII**

**Punitive Damages**

91. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 90 as if fully contained herein.

92. Pfizer denies each and every allegation contained in Paragraph 92 of the Complaint.

93. Pfizer denies each and every allegation contained in Paragraph 93 of the Complaint.

94. Pfizer denies each and every allegation contained in Paragraph 94 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' state of mind.

95. Pfizer denies each and every allegation contained in Paragraph 95 of the Complaint.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count VII of the Complaint.

**COUNT VIII**  
**Violation of G.B.L. § 349**

96. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 95 as if fully contained herein.

97. Paragraph 97 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 97 of the Complaint.

98. Pfizer denies each and every allegation contained in Paragraph 98 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' purchase of Viagra®.

99. Pfizer denies each and every allegation contained in Paragraph 99 of the Complaint.

100. Paragraph 100 of the Complaint contains legal conclusions to which no response is required. To the extent a response is required, Pfizer denies each and every allegation contained in Paragraph 100 of the Complaint.

101. Pfizer denies each and every allegation contained in Paragraph 101 of the Complaint, except denies knowledge or information sufficient to form a belief as to Plaintiffs' medical conditions, economic losses, or future needs.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count VIII of the Complaint.

**COUNT IX<sup>1</sup>**  
**Loss of Consortium**

102. Pfizer adopts and incorporates by reference its responses to Paragraphs 1 through 101 as if fully contained herein.

103. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 103 of the Complaint.

104. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 104 of the Complaint.

105. Pfizer denies knowledge or information sufficient to form a belief as to the allegations contained in Paragraph 105 of the Complaint.

Pfizer denies each and every allegation contained in the Wherefore Clause of Count IX of the Complaint.

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<sup>1</sup> Incorrectly denominated in the Complaint as Count IV.

### **PRAYER FOR RELIEF**

Pfizer denies each and every allegation contained in the Wherefore Clause of the Complaint, including subparts (d) through (i) thereof. In addition, Pfizer denies each and every allegation in the Complaint not specifically admitted herein. Pfizer further denies that Plaintiffs are entitled to any of the relief requested, and demands strict proof of each element of Plaintiffs' claims, and of Plaintiffs' claimed injuries and damages.

### **DEFENSES**

Pfizer lists the following defenses without conceding that it has the burden of proof as to any one of them.

#### **FIRST DEFENSE**

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

#### **SECOND DEFENSE**

2. Plaintiffs' claims are barred, in whole or part, because Viagra<sup>®</sup> is comprehensively regulated by the United States Food and Drug Administration pursuant to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder. Moreover, at all times, Viagra<sup>®</sup>'s labeling complied with all applicable FDA regulations and requirements. Accordingly, Plaintiffs' claims are barred by the doctrine of federal preemption.

#### **THIRD DEFENSE**

3. Plaintiffs' injuries or damages, if any, were, in whole or part, the result of conduct of the Plaintiffs, independent third parties, or events and/or conditions that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent of, or far removed, from Pfizer's conduct.



**FOURTH DEFENSE**

4. If Plaintiffs sustained any of the injuries or damages alleged in the Complaint, there was an intervening or superceding cause or causes leading to said injuries or damages and, as such, no action on the part of the Defendant was a proximate or producing cause of Plaintiffs' alleged injuries or damages.

**FIFTH DEFENSE**

5. Plaintiffs' claims are barred because the utility of the medication Viagra<sup>®</sup> outweighed the risk of its use.

**SIXTH DEFENSE**

6. Some or all of Plaintiffs' claims are barred by the equitable doctrines of waiver, estoppel and laches.

**SEVENTH DEFENSE**

7. Plaintiffs' claims are barred by the doctrines set forth in the RESTATEMENT (SECOND) OF TORTS § 402A, Comments j and k and/or RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY §§ 4 and/or 6.

**EIGHTH DEFENSE**

8. Plaintiffs' claims are barred by the "learned intermediary" or "informed intermediary" doctrine or similar applicable laws.

**NINTH DEFENSE**

9. Plaintiffs' claims are barred or limited by the doctrine of comparative or contributory fault.

**TENTH DEFENSE**

10. Any alleged injuries were caused by pre-existing or unrelated medical, genetic, or environmental conditions, diseases, or illnesses, or through natural causes or an unforeseeable idiosyncratic reaction peculiar to the Plaintiffs.

**ELEVENTH DEFENSE**

11. Plaintiffs' claims are barred by Sections 6(c) and (d) of the RESTATEMENT (THIRD) OF TORTS: Products Liability. Reasonable physicians knowing of the reasonably foreseeable risks and therapeutic benefits associated with Viagra<sup>®</sup> would have prescribed and did prescribe Viagra<sup>®</sup> for classes of patients. In addition, Pfizer provided reasonable instructions or warnings to prescribing physicians.

**TWELFTH DEFENSE**

12. Plaintiffs' claims are barred, in whole or part, because Plaintiffs, by electing to ingest Viagra<sup>®</sup>, assumed the risks disclosed on Viagra<sup>®</sup>'s FDA-approved label, and Plaintiffs waived and/or are estopped from asserting any claim related to such risks.

**THIRTEENTH DEFENSE**

13. Plaintiffs' damages, if any, are limited, in whole or part, by Plaintiffs' failure to mitigate or reasonably avoid their alleged damages.

**FOURTEENTH DEFENSE**

14. Plaintiffs' claims are barred, in whole or part, by Plaintiffs' misuse of Viagra<sup>®</sup>.

**FIFTEENTH DEFENSE**

15. Some or all of the Plaintiffs' claims are barred by the applicable statutes of limitations and/or repose.

**SIXTEENTH DEFENSE**

16. Plaintiffs' claims are barred, in whole or in part, by the doctrines of merger, bar, collateral estoppel, res judicata, release, discharge, and accord and satisfaction.

**SEVENTEENTH DEFENSE**

17. Plaintiffs' claims are barred because Viagra<sup>®</sup> was designed, manufactured and marketed in accordance with the state-of-the-art. The methods, standards and techniques utilized in manufacturing Viagra<sup>®</sup>, and in issuing warnings and instructions with respect to its use, conformed with the generally recognized, reasonably available, and reliable state of knowledge and standards of the industry at the time Viagra<sup>®</sup> was manufactured and marketed. Viagra<sup>®</sup> was and is safe for its intended use and it was not and is not defective or unreasonably dangerous.

**EIGHTEENTH DEFENSE**

18. Pfizer did not make to Plaintiffs nor did it breach any warranties and did not breach any warranties created by law. Plaintiffs lacked the necessary privity with Pfizer to maintain their claims for breach of warranty and failed to give timely notice to Pfizer barring the claims, as required by law. Furthermore, Plaintiffs' claims for breach of warranty may be barred by a failure to follow warranty procedures and satisfy conditions precedent.

**NINETEENTH DEFENSE**

19. Pfizer was in compliance with legislative regulatory standards and/or administrative regulatory safety standards relating to warnings and/or instructions and design and/or performance and, therefore, Viagra<sup>®</sup> is deemed not defective.

**TWENTIETH DEFENSE**

20. Plaintiffs' claims are barred, in whole or in part, because public policy favors the development and marketing of beneficial new medications.

**TWENTY-FIRST DEFENSE**

21. Plaintiffs' claims are barred, in whole or in part, because the FDA-approved labeling with respect to Viagra<sup>®</sup> was not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution and the applicable provisions of the Constitution and laws of the State whose law governs.

**TWENTY-SECOND DEFENSE**

22. Plaintiffs cannot recover to the extent their damages are covered or reasonably likely to be covered by insurance or other collateral source or, in the alternative, their damages should be offset or reduced by insurance or collateral source payments and benefits.

**TWENTY-THIRD DEFENSE**

23. Plaintiffs' claims based on fraud are barred because they have not been pled with sufficient particularity and specificity to meet the requirements of Federal Rule of Civil Procedure 9(b).

**TWENTY-FOURTH DEFENSE**

24. The action should be transferred to another venue pursuant to the doctrine of *forum non conveniens*, under 28 U.S.C. §1404.

**TWENTY-FIFTH DEFENSE**

25. Plaintiffs' claims for punitive or exemplary damages are improper pursuant to the applicable state law because there has been no showing by evidence in the record that the applicable standards required for an averment of such damages has been met.

**TWENTY-SIXTH DEFENSE**

26. Plaintiffs' claims for punitive damages are barred because any award of punitive damages would violate Pfizer's rights guaranteed by the United States Constitution, including without limitation, the Due Process and Equal Protection provisions of the Fourteenth

Amendment of the United States Constitution, and the applicable provisions of the Constitution and laws of the State whose law governs.

**TWENTY-SEVENTH DEFENSE**

27. To the extent California law applies, Pfizer's liability, if any, for non-economic damages is several rather than joint, and should be prorated according to California Civil Code §1431.2 or otherwise.

**TWENTY-EIGHTH DEFENSE**

28. To the extent Arizona law applies, Plaintiffs' claim for punitive damages is improper pursuant to Ariz. Rev. Stat. Ann. § 12-701, which bars the imposition of punitive damages in cases involving FDA-approved products.

**TWENTY-NINTH DEFENSE**

29. Pfizer invokes each and every statutory and common law defense available to it under applicable law.

**THIRTIETH DEFENSE**

30. Pfizer reserves the right to raise additional affirmative and other defenses as may be established by discovery and the evidence in this case.

**DEMAND FOR JURY TRIAL**

Pfizer demands a jury trial on all claims so triable in the action.

WHEREFORE, having fully answered, Pfizer demands that Plaintiffs' Complaint be dismissed with prejudice and that it recover against the Plaintiffs its costs herein expended and grant any and all other remedies to which it may be entitled to under law.

**KAYE SCHOLER LLP**

Date: May 16, 2008

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**ATTORNEYS FOR DEFENDANT PFIZER  
INC.**